UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 6, 2011

MEMORANDUM

SUBJECT: Efficacy Review for BRACE;
EPA Reg. No. 777-99;
DP Barcode: D392480

FROM: Karen M. Hill, Ph.D.
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APPLICANT: Reckitt Benckiser LLC
Morris Corporate Center IV
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Formulation from the Label:

Active Ingredient(s):	% by wt.
Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium saccharinate...	00.10%
Ethanol.....	58.00%
Inert Ingredients.....	41.90 %
Total.....	100.00 %

I BACKGROUND

The product, BRACE (EPA Reg. No. 777-99), is an EPA-approved disinfectant (bactericide, tuberculocide, fungicide, virucide), sanitizer, mildewcide, and deodorizer for use on hard, non-porous surfaces in household, institutional, commercial, food preparation, animal care, and hospital or medical environments. [The product is also for use on soft surfaces.] The applicant requested to amend the registration of this product to add a new alternate formulation that has a new fragrance ingredient. The applicant provided confirmatory efficacy data for the new alternate formulation. The study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated May 5, 2011), EPA Form 8570-35 (Data Matrix), one study (MRID 484738-01), a Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary for the study.

The laboratory report describes a study conducted for the product, Festivus V, Formula #1784-045A. The applicant's letter to EPA (dated May 5, 2011) states that the tested product, Festivus V, Formula #1784-045A, is the new alternate formulation of the product, BRACE, which is the subject of this efficacy report.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: appliances, bathtubs, bed frames, bed springs, bidets, blinds, cabinets, cages, chairs, changing tables, clean-up carts, counters, cribs, cuspidors, desks, diaper pails, dish pails, doorknobs, drains, dressing carts, drinking fountains, examination tables, faucets, fixtures, floors, furniture, garbage cans, garbage pails, highchairs, kennels, lamps, laundry hampers, light switches, linen carts, litter boxes, mattress covers, mirrors, outdoor patio furniture, pens, recycling bins, remote controls, salad bar sneeze guards, showers, sinks, sports equipment, stretchers, tables, telephones, toilets, tools, toys, walls, wheelchairs, whirlpool interiors, and windows. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: crystal, cultured marble, enamel, glass, glazed ceramic, glazed porcelain, glazed tile, laminated surfaces, linoleum, Marlite, metal (i.e., brass, chrome, copper, stainless steel, tin), Parquet, plastic, sealed granite, synthetic marble, and vinyl.

Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Pre-clean surfaces prior to use. Hold container upright 6-8 inches from surface. Spray 2 to 3 seconds until covered with mist. Let stand for 10 minutes. Allow to air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use in Hospital or Medical Environments; Confirmatory Efficacy Data Requirements:

Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce

an effective formation. Confirmatory data must be developed on the applicants own finished product. For hospital disinfectants, 10 carriers on each of 2 samples representing 2 different product lots must be tested against *Salmonella enterica* (ATCC 10708, formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442) using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Killing on all carriers is required.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 484738-01 "AOAC Germicidal Spray Method," Test Organisms: *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442), test substance Festivus V, Formula #1784-045A, study director is Joshua Luedtke. Study conducted at ATS Labs. Study completion date – April 11, 2011. Study Identification Number A11032.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 1784-052 and 1784-054) of the product, Festivus V, Formula #1784-045A, were tested using included ATS LABS Protocol No. REK01020711.GS. The product was received ready-to-use, as an aerosol spray. Cultures of the challenge microorganisms were prepared in accordance with ATS LABS Protocol No. REK01020711.GS. *Pseudomonas aeruginosa* culture was incubated for 51 hours at 35-37°C. The pellicle was aspirated from the *Pseudomonas aeruginosa* culture on the day of use. The cultures for *Staphylococcus aureus* and *Salmonella enterica* were incubated for 51 hours at 35-37°C. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot per microorganism were inoculated with 10.0 µL of a 51 hour old suspension of test organism. Inoculum was uniformly spread over the entire surface of each carrier. The carriers were dried for 30-38 minutes at 35-37°C at 66% relative humidity. For each lot of product, separate carriers were sprayed (2 seconds) with the product from a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 10 minutes at 21°C at 5% relative humidity. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Letheen Broth with 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures and controls were incubated for 46 hours at 35-37°C. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls for both product lots included those for carrier population, purity, sterility, viability, and neutralization confirmation.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (Geometric Mean; CFU/carrier)
		Lot No. 1784-052	Lot No. 1784-054	
484738-01	*Staphylococcus aureus*	0/10	0/10	6.76×10^6
	Salmonella enterica	0/10	0/10	4.90×10^4
	Pseudomonas aeruginosa	0/10	0/10	7.94×10^6

VI CONCLUSIONS

1. The submitted confirmatory efficacy data support the use of the product, Festivus V, Formula #1784-045A, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 10-minute contact time:

Staphylococcus aureus	MRID 484738-01
Salmonella enterica	MRID 484738-01
Pseudomonas aeruginosa	MRID 484738-01

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. Confirmatory data demonstrate that the new alternate formulation of the product, BRACE, is an effective disinfectant against *Pseudomonas aeruginosa*, *Salmonella enterica*, and *Staphylococcus aureus* on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time.